AUG 2 2 2000

510(K) SUMMARY

Col-Bar Ltd.

BIOBAR Biodegradable Collagen Membrane

510(k) Number K 001598

Applicant's Name: Col-Bar Ltd.
86 Sokolov St.
Ramat-Hasharon 47232, Israel
Tel: 972-3-5470804
Fax: 972-3-5470944

Contact Person: Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
Fax: (202) 637-5910

Date Prepared: January 2000

Trade Name: BIOBAR™

Classification Name:
Endosseous Implant for Bone Filling and/or Augmentation

Classification: To the best of our knowledge, FDA has not classified this device, although it has assigned a product code of LYC in the Classification Database and it is reviewed by the Dental Devices Panel.

Predicate Devices: Col-Bar Ltd. believes that the BIOBAR Biodegradable Collagen Membrane is substantially equivalent to BioMend Absorbable Collagen Membrane (Integra LifeScience Corporation) cleared under K924408, the Gore Resolut XT Regenerative Material Cleared under K973594 (W.L. Gore and Associates, Inc.) and the Bio-Gide Resorbable Bilayer Membrane cleared under K960724 (Geistlich Pharma).

Indication for Use: **BIOBAR** Biodegradable Collagen Membrane is intended for use during the process of guided bone regeneration as a biodegradable

membrane for supporting: Augmentation around implants placed in immediate extraction sockets; ridge augmentation for later implantation; and alveolar ridge reconstruction for prosthetic treatment.

BIOBAR must be used in conjunction with space-making bone graft material (e.g., autogenous bone or bone substitutes).

Device Description:

BIOBAR is a biodegradable membrane aimed to support the formation of new alveolar bone for restorative and/or cosmetic purposes when the technique of guided bone regeneration is utilized. BIOBAR consists of purified type I collagen extracted from bovine tendons. BIOBAR has a porous structure with average pore size of 1μ in diameters to occlude gingival cells passage and permits fluids and plasma proteins passage. BIOBAR is not self-supporting and as such it is recommended for use in conjunction with an autogenous bone graft or an allograft or a xenograft or an osteoconductive and/or inductive bone substitute or a mixture of these.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Safety and Effectiveness:

The biological safety of the BIOBAR Biodegradable Collagen Membrane has been assured through biocompatibility studies.
The effective performance of the BIOBAR Biodegradable Collagen Membrane has been established through in vitro, animal and clinical studies

Substantial Equivalence:

Based on a series of safety and performance testing, including animal and clinical studies, we believe that the BIOBAR Biodegradable Collagen Membrane is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2000

Col-Bar Limited
C/O Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, North West
Washington, DC 20004

Re: K001598
Trade Name: Biobar Biodegradable Collagen Membrane
Regulatory Class: Unclassified
Product Code: LYC
Dated: May 23, 2000
Received: May 23, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K001598

Device Name: BIOBAR Biodegradable Collagen Membrane

Indications for Use:

BIOBAR Biodegradable Collagen Membrane is intended for use during the process of guided bone regeneration as a biodegradable membrane for supporting: Augmentation around implants placed in immediate extraction sockets; ridge augmentation for later implantation; and alveolar ridge reconstruction for prosthetic treatment.

BIOBAR must be used in conjunction with space-making bone graft material (e.g., autogenous bone or bone substitutes).

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001598